

### **REMARKS/ARGUMENTS**

Claims 1-35 and 37-42 are pending in this application. Claims 8 and 9 have been amended to correct a typographical error therein such that the claims now specifically recite the number of the claim from which they depend. No new matter is added by these amendments.

Attached to the Office Action is a copy of the form PTO-1449 that was included with the application papers at the time this case was filed. Several of the documents cited on the form have been crossed out by the Examiner. She indicated on the form that copies of the crossed out documents were not provided with the application papers. Submitted herewith, therefore, is a form PTO-1449 which lists each of the documents crossed out by the Examiner on the original form, together with a copy of each of these documents. The Examiner is, therefore, respectfully invited to review the enclosed materials and to make them of record in the application.

### **Claim Rejections Under 35 U.S.C. §103**

Claims 1-24 and 37-41 are rejected under 35 U.S.C. §103 as being allegedly unpatentable over Kropf et al. DE 10063945 A1 in view of Greenberg et al. U.S. Patent No. 5,980,955. The Office Action states, with regard to the Kropf et al. reference, that the published DE 10063945 A1 is a priority document for Kropf et al. Published U.S. Application No.2003/0219388 A1 and that the U.S. document is used as an English-language equivalent to the German publication. The rejection of claims 1-24 and 37-41 is respectfully traversed.

Claim 1 is the only one of the rejected claims that is written in independent form. The claim recites a chewing gum coated by at least one layer, the layer comprising a coating material selected from the group consisting of slightly water soluble calcium salts and composites thereof, wherein the slightly water-soluble calcium salt has a particle size of less than 1000 nm, Claims 2-24 and 40-41 further define the chewing gum of claim 1. Claim 37 is directed to a method for improving dental hygiene in a subject in need thereof that comprises chewing by the subject of the chewing gum according to claim 1. Claim 38 recites a method for mineralizing the tooth enamel of a subject in need thereof which comprises chewing by the subject of the chewing gum according to claim 1. Claim 39 is directed to a method for mineralizing the dentine of a subject in need thereof which comprises chewing by the subject of the chewing gum according to claim 1.

The same two references are, moreover, relied upon to also reject the remaining claims of this application. More particularly, claims 25 - 35 and 42, which recite a method for producing the chewing gum of claim 1, are rejected under 35 U.S.C. §103 as being allegedly unpatentable over Greenberg et al. in view of Kropf et al. This rejection is also respectfully traversed.

The rejection of claims 1-24 and 37-41 is directed against claims reciting a composition of matter, i.e., a chewing gum, and to methods for using the composition, i.e., for improving dental hygiene, for mineralizing tooth enamel and for mineralizing dentine. The next rejection, i.e., of claims 25-35 and 42, involves claims which recite a method for making the gum of claim 1. Since both rejections involve the same references and related subject matter, therefore, the remarks set forth below address both rejections together. This is for purposes of avoiding prolixity, i.e., involving duplication of the arguments, e.g., wherein the same ground of distinction is argued against both rejections. That is, the distinguishing features of all of applicants' claims are discussed all together in the following remarks.

First, with regard to Greenberg et al., the Greenberg reference discloses coated chewing gum products that are characterized by a coating composition comprising a small quantity of a food-acceptable poorly water soluble calcium salt, added for improving the smoothness of the finished coating and thereby providing an improved appearance to the gum product (see, e.g., col. 1, lines 5-21). According to the disclosure contained at, e.g., col. 2, lines 56-67, the salts have a solubility in water having a temperature of about 10°C of from about 0.5% to about 9%.

At the coating temperatures conventionally used for coating chewing gums (see, e.g., the Examples provided in the Greenberg reference) calcium salts as described in the Greenberg et al. reference are either completely, or almost completely, dissolved. This permits use of the calcium salts as crystallization germs during coating, i.e., which involves the successive application of a plurality of coating layers which are each dried, following each application, by evaporation of the water contained therein. Further in regard to the above, see Col. 8, lines 20-25 which describe a syrup temperature of 85°C in the coating step and which additionally teach alternately spraying and drying the syrup coating layers.

In contrast to the teachings contained in Greenberg, the disclosure in Kropf et al. does not relate to the preparation of chewing gums, which leads to the conclusion that the combination of

Kropf with Greenberg is not obvious as suggested by the Examiner. Kropf et al. deals with dental adhesive films, rather than chewing gums. According to p. 4, ¶45 of 2003/0219388, the dental adhesive films are prepared by adding specific poorly soluble nano-particle size calcium salt to a solution of a polymeric carrier material to form a dispersion and subsequently drying the resultant dispersion to obtain the film. The dental adhesive film of Kropf et al. thus comprises a polymeric film containing a specifically required calcium salt. The nano-particle size calcium salt has a solubility of less than 0.1 wt. % at 20°C, which is much lower than the salts described in the Greenberg et al. reference. Applicants thus reiterate their view that Kropf et al. is not combinable with Greenberg since, *inter alia*, Kropf teaches away from such a combination by its disclosure of a very specific system, different from that disclosed in Greenberg et al., which instead of producing a gum results in the production of dental adhesive films wherein a calcium salt (of a size different than that used in Greenberg et al.) is incorporated within a polymeric carrier material, and wherein the method used in Kropf et al. to form the film is entirely different than the method used by Greenberg to form a gum.

Further to the statement above that the system disclosed in Kropf et al. for forming the film is totally different than that used in Greenberg et al. to form a gum, applicants note that the coating process for the chewing gums described in Greenberg et al. relies on controlled application of a coating medium to a core, which involves multiple application and drying step sequences. During the process the coating medium applied and thus sticking to the core successively reduces its moisture content. Additionally, the ingredients such as the calcium salts and xylitol successively crystallize out in order to form the desired crystalline coating layer. Such a system clearly requires, therefore, an ability to recrystallize and therefore, also requires at least a partial solubility of its coating material, i.e, in the present case calcium salts, in the coating medium in order that the coating material can be applied in a completely or a partially dissolved form, whereupon it can thereafter crystallize out during the subsequent drying step.

The calcium salts disclosed in Kropf et al., however, demonstrate a solubility which is significantly below the solubility of the corresponding salts used in the process disclosed by the Greenberg reference. In this regard, the Examiner's attention is respectfully directed to the paragraph bridging cols. 1-2 of the Greenberg et al. reference which sets forth the patentees'

theory concerning how the poorly water soluble calcium salt used in the Greenberg et al. reference operates. That is, as suggested in the reference, the authors believe that the poorly water soluble salt may ‘come out of solution’ (i.e., it had been dissolved) at the right time to promote a quick crystallization by seeding the syrup. Thus, the effect of the calcium salt mentioned in Greenberg et al. relies on its solubility in the coating medium and the proper recrystallization behavior to permit it to precipitate at the correct time and in the correct quantity to permit proper crystallization of the other coating material contained in the medium.

In the first full paragraph in col. 2 of the reference (i.e., beginning at line 13) the patentees of the Greenberg et al. patent further speculate that the poorly water soluble salt may form an initial co-crystal with the other coating material contained in the medium. Also in accordance with the theory advanced by the patentees at that location in the specification, the solubility of the calcium salt in the coating medium and its recrystallization are proper functioning (see also, col. 2, lines 45-46 of Greenberg et al.).

In contrast to the teachings contained in Greenberg et al., the nano-particle sized calcium salts disclosed in the Kropf et al. reference would not be suitable, due to their extremely low solubility, to function as crystallization germs in a chewing gum coating process. One having ordinary skill in the relevant art would not have believed, at the time the present invention was made, that the calcium salts described in Kropf et al. would dissolve sufficiently enough in a coating medium under the ‘environmental’ conditions described in the reference. Thus, such an individual would have believed that the subject material would not be suitable to be applied, in an at least partially dissolved form, in a coating medium on chewing gums.

Furthermore, the process of preparing the dental adhesive film described in Kropf et al. is not only different from the process described in Greenberg et al., it is even further from that described and claimed for use in the case of the present invention. That is, there is no requirement in the process according to Kropf et al. for a controlled recrystallization from a medium on a substrate. In addition, the system described by Kropf et al. requires the use of specific polymers which, as would be readily understood by one having at least ordinary skill in the relevant art, would clearly not be appropriate for inclusion in any conventional chewing gum.

There is, thus, no motivation for one having ordinary skill to assume that the extremely low-soluble nanoparticle sized salts disclosed for use in Kropf et al.- which apparently are only suitable for use in the very specific application described in the reference of producing a dental adhesive film, and then only in the presence of certain specific polymers - would be suitable to be applied as a coating ingredient for chewing gum cores, particularly in view of the fact that such coating ingredients require a certain solubility and a specific recrystallization capability not taught by the subject reference, i.e., as these parameters are not requirements for the dental adhesive film taught therein. In particular, the specific solubility and recrystallization requirements set forth in col. 2 of the Greenberg et al. reference teach to one of skill in this art that not all calcium salts known in the art may be used in the Greenberg et al process. Instead, the only ones of these which may be used are those specific ones which meet the proper crystallization requirements sought by the Greenberg et al. inventors. There is no hint in the subject reference that the calcium salts described in the Kropf et al. reference, which has been combined with Greenberg would fulfill the specific requirements set forth in Greenberg et al.

There would, therefore, be no reasonable expectation of success if one were to choose from among the calcium salts described in Kropf et al., which are known to be much less soluble than the poorly water soluble salts of Greenberg et al., as substitutes for use in the coating process described in Greenberg et al.

Still further, the written description of applicants' invention demonstrates that the calcium salts as recited in, e.g., present claim 1 provide a surprisingly advantageous effect on the health of the teeth of one who chews a chewing gum according to the claims of the present application. The Greenberg reference describes no such advantages as are obtained with the use of applicants' gum, choosing to focus instead only on the organoleptic aspects of the chewing gum coatings described therein.

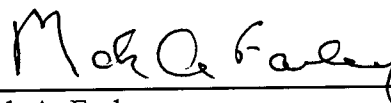
To summarize, Greenberg et al. teaches one to use specific calcium salts for purposes of providing an improved appearance to a chewing gum coating. There is no hint or motivation contained in the subject reference to replace the specific calcium salts with the nanoparticle sized calcium salts described in the Kropf et al. reference to obtain a chewing gum that is of benefit to the dental health of one who chews the gum described in the Greenberg reference. This is, in

particular, due to the fact that as noted above the calcium salts disclosed in Greenberg are included for a very specific purpose and are obviously selected to meet the specific requirements described in col. 2, first paragraph of the Greenberg et al. reference. Therefore, the salts described in Kropf et al. which differ from those described in Greenberg et al., e.g., in both their size and solubility, would not meet the criteria required for the salts in the Greenberg reference.

Applicants thus submit that the rejected claims of the present application are believed to be patentably distinct over the combined disclosure of Greenberg et al. and Kropf et al. whose disclosures serve to actually teach away from their combination and that, as such, the Examiner is respectfully requested to reconsider and withdraw the rejections under 35 U.S.C. §103 of the subject claims based on the cited combination of references.

THIS CORRESPONDENCE IS BEING  
SUBMITTED ELECTRONICALLY  
THROUGH THE PATENT AND  
TRADEMARK OFFICE EFS FILING  
SYSTEM ON September 22, 2008.

Respectfully submitted,



---

Mark A. Farley  
Registration No.: 33,170  
OSTROLENK, FABER, GERB & SOFFEN, LLP  
1180 Avenue of the Americas  
New York, New York 10036-8403  
Telephone: (212) 382-0700

MAF:stb